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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/645,810 08/21/2003		Scott Andrew Ciarrocca	GYN-5004 7879		
27777 7590 08/10/2006			EXAMINER		
PHILIP S. JOHNSON			VRETTAKOS, PETER J		
JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			ART UNIT	PAPER NUMBER	
			3739		
			DATE MAILED: 08/10/200	DATE MAILED: 08/10/2006	

Please find below and/or attached an Office communication concerning this application or proceeding.

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	•	<b>A</b>	Application No.	Applicant(s)			
Office Action Summary			10/645,810	CIARROCCA, SCOTT ANDREW			
		E	Examiner	Art Unit			
			Peter J. Vrettakos	3739			
	The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).							
Status							
1) 又	Responsive to communication(s) file	ed on 26 July	2006.				
, —	This action is <b>FINAL</b> . 2b)⊠ This action is non-final.						
· -	Since this application is in condition	•		secution as to the merits is			
,_	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Dispositi	on of Claims						
4)🖂	4) Claim(s) 1-21 is/are pending in the application.						
	4a) Of the above claim(s) is/are withdrawn from consideration.						
5)	Claim(s) is/are allowed.						
6)⊠	Claim(s) <u>1-7 and 9-21</u> is/are rejected.						
7)🖂	Claim(s) 8 is/are objected to.						
8)□	8) Claim(s) are subject to restriction and/or election requirement.						
Applicati	on Papers						
9) 🗌	The specification is objected to by the	e Examiner.					
10)	The drawing(s) filed on is/are:	a) accept	ted or b) $\square$ objected to by the E	xaminer.			
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).							
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.							
Priority u	ınder 35 U.S.C. § 119						
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>							
Attachmen	t(s)						
1) Notice of References Cited (PTO-892)			4) Interview Summary				
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 11-#03.			Paper No(s)/Mail Da 5) Notice of Informal Pa 6) Other:	te atent Application (PTO-152)			

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#### **DETAILED ACTION**

RCE filed 7-6-06.

Amendments and clarifying arguments have obviated prior rejections. New art is presented below. The prior art neglects to disclose a converting element as currently disclosed by the Applicant.

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7, 9-17 and 20-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Bencini et al. (6,666,864).

Bencini discloses a bipolar electrosurgical instrument (see figure 3) comprising:

- a handle (16);
- a shaft (12);
- a converting element (44) including a concentrically disposed (deduced from figure 3) electrically conductive portion (48), the element slidably movable between several (including "first" and "second") positions wherein 48 is in contact with different electrodes (20) changing the effective (energized) surface area of the electrode (20) to

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which 48 is in contact as well as substantially changing the relative effective (energized) surface areas between the energized electrode and the non-energized (non-contacted with 48) electrodes, and wherein the instrument uses bipolar energy (col. 5:59-63) regardless of the electrode (20) that is energized (in contact with 48) using an electrosurgical generator (see patented claim 17).

Note: electrodes (20) can be designated "return" or "active" electrodes. Further, these two terms ("return" and "active") speak toward the *intended use* of the device (the electrode): a recitation of the intended use of the claimed invention must result in a *structural difference* between the claimed invention ("active" electrode and "return" electrode) and the prior art (electrodes 20) in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is *capable* of performing the intended use, then it meets the claim. The Office asserts no structural difference exists between patented electrodes 20 and the Applicant's claimed electrodes.

Figure 12 discloses a fluid delivery channel (94, 88) and outlets (90 and 84) enabling the Bencini device to create lesion **L**. Further, the same structure for fluid delivery is *capable* of vacuum. (The prior art is replete with electrosurgical units with interchangeable irrigation and suction abilities.) As such the Office asserts, consistent with the intended use rationale applied in the preceding paragraph, that Bencini discloses a vacuum delivery system with inlets (94, 88) and outlets (90 and 84).

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Bencini discloses treatment for more than one type of tissue (col. 4:25-28) as well as targeting tissue in more than one position (of the electrical conductive portion element 48) (col. 7:9-13) in order to create lesions of various lengths.

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 18 and 19 rejected under 35 U.S.C. 103(a) as being unpatentable over Bencini et al. (6,666,864).

Bencini is silent regarding whether one position (of element 48) is better for cutting or for coagulation. However, these characteristics of the method disclosed by Bencini would be determined through routine experimentation motivated by the normal desire of artisans to improve upon what is already known. What is known in this instance is the structure/device disclosed by Bencini and its straightforward method of use. (Routine experimentation would yield/make obvious the Applicant's claims – which positions of element 48 are better for cutting and which for coagulation). The relevant MPEP section is: 2144.05 II.A.

#### Optimization Within Prior Art Conditions or Through Routine Experimentation

Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which

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differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), *cert. denied*, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

Although the MPEP section is toward differences in concentration and temperature, the principles evinced in the section apply to the instant case because the Applicant's claims are slight variations to what is disclosed, which is a straightforward method of use of the structurally equivalent Bencini device.

Furthermore, the Office asserts that the claims as currently read are more so discoveries (ex. one position works better for cutting than coagulate) that have arisen from use of the claimed device. The MPEP addresses this as well. MPEP § 2122 I:

# SOMETHING WHICH IS OLD DOES NOT BECOME PATENTABLE UPON THE DIS-COVERY OF A NEW PROPERTY

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). >In In re Crish, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court held that the claimed promoter sequence obtained by sequencing a prior art plasmid that was not previously sequenced was anticipated by the prior art plasmid which necessarily possessed the same DNA sequence as the claimed oligonucleotides. The court stated that "just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel." Id. See also MPEP § 2112.01 with regard to inherency and product-by-process claims and MPEP § 2141.02 with regard to inherency and rejections under 35 U.S.C. 103.

To these ends, the Office asserts that Bencini's disclosure sufficiently makes obvious the Applicant's claims that one position is better than another for cutting as well as coagulation because the "discovery" would be determined through routine experimentation motivated by a "normal desire" to improve upon what is already known. Even without routine experimentation, however, the Office argues that claims 18 and 19

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are discoveries, which as mentioned in the MPEP section above do not render the old composition (the method of use of the structurally equivalent Bencini device) "patentably new to the discoverer".

### Allowable Subject Matter

Claim 8 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Vrettakos whose telephone number is 571-272-4775. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Pete Vrettakos August 6, 2006

ROY D. CIBSON PRIMARY EXAMINER